REMARKS

Reconsideration of the present application is respectfully requested, in view of the remarks that follow. This application includes claims 39-53, 57, 60, 74-76 and 87-94, pending and under consideration. No amendments to the claims are being made in this Response.

As an initial matter, Applicant acknowledges and thanks the Examiner for the indication in the outstanding Action that all previously-asserted rejections are withdrawn. As discussed fully hereinbelow, Applicant submits that the newly-cited references disclose nothing more pertinent than the previously-cited references, and that the same rationale presented in Applicant's prior response supports the withdrawal of all art rejections asserted in the present Action also.

At the time the outstanding Office Action was mailed on April 18, 2007, claims 39-53, 57, 60, 74-76 and 87-94 were pending and under consideration and claims 39-53, 57, 60, 74-76 and 87-94 stand rejected. Reconsideration of the present application, in view of the remarks herein, is respectfully requested. For the reasons set forth herein, the Applicant submits that, and respectfully requests an indication that, pending claims 39-53, 57, 60, 74-76 and 87-94 are in condition for allowance.

Claim Rejections – 35 USC §112, first paragraph

In the outstanding Office Action, claims 39-53, 57, 60, 74-76 and 87-94 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. In support of this rejection, the Action states that the following "negative proviso" in the claims is not supported by the specification: "wherein the dispenser is not an aerosol device." The Office Action cites no authority for this assertion, and Applicant believes that this rejection is unsupported by any legal authority. Indeed, with reference to the third paragraph of Section 2173.05(i) of the Manual of Patent Examining Procedure ("MPEP"), Applicant submits that the negative proviso identified in the Action is acceptable because alternative dispenser elements are positively recited in the specification of the present application, and a claim encompassing subject matter that excludes one or more of

the alternative elements recited in the specification satisfies the written description requirement of Section 112, first paragraph.

The third paragraph of MPEP §2173.05(i) addresses how the written description requirement of Section 112, first paragraph, is to be applied to the recitation of a negative limitation in a claim, stating that, "[i]f alternative elements are positively recited in the specification, they may be explicitly excluded in the claims." (citing *In re Johnson*, 194 USPQ 187, 196 (CCPA 1977)). In support of this position, the Court in *In re Johnson* states that "[the] specification, having described the whole, necessarily described the part remaining."

In the present case, alternative elements are described in the specification for the dispenser element recited in claim 39. Specifically, the specification describes at least the following alternative dispensers: (1) an atomizing pump spray dispenser (*See* Patent Application Publication No. 2005/0079229, Paragraphs 60 *et seq.*), (2) a pressure release device (*See* Paragraph 63 of the published application) (3) a piston-style pressure release device, which can operate, for example, by gas pressure or by spring pressure (*See* Paragraph 64 of the published application), (4) a bag-in-can-style dispenser, which can operate, for example, by gas pressure on the bag or by using a shape-memory bag that exerts pressure on the material contained in the bag (*See* Paragraphs 65 *et seq.* of the published application), and (5) an aerosol device (*See* Paragraph 67 of the published application).

Because the application recites alternative elements for the dispenser element in claim 39, and applying the rule set forth in the third paragraph of MPEP §2173.05(i), Applicant submits that the recitation of the "negative proviso" identified in the Action, excluding one of the alternative elements, satisfies the written description requirement of Section 112, first paragraph.

In the Action, the Examiner states that, "Moreover, the Applicant defines the aerosol device as 'another atomizing spray dispenser that may be used in accordance with the invention' (see page 25, paragraph 3, lines 1-3)." In view of the above-discussed rule set forth in MPEP §2173.05(i), this statement in the Action does not support or advance the rejection, but rather identifies an aerosol device as one embodiment that can be excluded from the claim using a negative limitation as Applicant has done.

In view of the above, Applicant submits that the rejection of claims 39-53, 57, 60, 74-76 and 87-94 under Section 112, first paragraph, is improper and must be withdrawn.

Claim Rejections – 35 USC §102

In the outstanding Office Action, claims 39, 49, 57, 74, 76 and 88 are rejected under 35 U.S.C. §102 as being anticipated by U.S. Patent No. 3,079,299 to Heilig (hereafter, "the Heilig patent"). In traversal of this rejection, Applicant submits that the Heilig patent discloses subject matter that is no more pertinent to the present claims than that disclosed in the previously-cited Adams reference, and fails to support a rejection of the pending claims for the same reasons that the Adams reference fails to support a rejection of the claims (Applicant notes that the Examiner has withdrawn all prior rejections based on the Adams reference). Specifically, the Heilig patent discloses an aerosol delivery system for applying a medicinal ointment. As stated in the Heilig patent, "This invention relates to improvements in medicinal ointment compositions and more particularly to such compositions including an ointment base of mineral oil containing dispersed polyethylene resin and *a volatile propellant* for dispensing and applying the medicinal ointment to the part of the body to be treated." (Column 1, lines 11-16) (emphasis added). In addition, the Heilig patent states that, "...the base is incorporated as an ingredient *in an aerosol medicinal ointment composition* and applied to an affected area of the body." (Column 2, lines 4-6) (emphasis added). Because the Heilig patent, like the Adams reference, describes a composition delivered by an aerosol delivery mechanism, Applicant submits that it cannot and does not anticipate independent claim 39, which recites that "the dispenser is not an aerosol device."

Each of claims 49, 57, 74, 76 and 88 depends from independent claim 39, and claims 49, 57, 74, 76 and 88 therefore satisfy the novelty requirement of Section 102 for at least the same reasons that claim 39 satisfies the novelty requirement, and for other reasons.

In view of the above, Applicant submits that each of the identified claims recites subject matter that is novel over Heilig, and respectfully requests withdrawal of this rejection under 35 U.S.C. §102.

Claim Rejections – 35 USC §103

In the outstanding Office Action, pending claims 40-53, 60, 74, 75, 87 and 89-94 stand rejected as being unpatentable under 35 U.S.C. §103(a) over various combinations of references. In particular, claims 40-50, 52, 53 and 60 are rejected in the outstanding Action as being unpatentable over the Heilig reference in view of U.S. Patent No. 6,217,890 to Paul et al. (hereafter "the Paul reference"); claims 51 and 52 are rejected under 35 U.S.C. §103(a), as being unpatentable over the Heilig reference in view of U.S. Patent No. 5,330,756 to Steuart et al. (hereafter "the Steuart reference"); claims 74, 75, 87, 89, 93 and 94 are rejected under 35 U.S.C. §103(a), as being unpatentable over the Heilig reference in view of U.S. Patent No. 5,881,925 to Ando (hereafter "the Ando reference"); claims 90 and 91 are rejected under 35 U.S.C. §103(a), as being unpatentable over the Heilig reference in view of U.S. Patent No. 5,169,037 to Davies et al. (hereafter "the Davies patent"); and claims 90 and 92 are rejected under 35 U.S.C. §103(a), as being unpatentable over the Heilig reference in view of U.S. Patent No. 5,249,747 to Hanson et al. (hereafter "the Hanson reference").

Applicant initially points out that each of the claims rejected under Section 103(a) depends, directly or indirectly, from independent claim 39. For the reasons set forth above, the only ground for rejecting claim 39 set forth in the Action has been overcome and claim 39 is in condition for allowance. It is axiomatic that all dependent claims depending from an allowable base claim are also allowable for at least the same reasons that the independent claim is allowable. As such, Applicant submits that the rejections of dependent claims 40-53, 60, 74, 75, 87 and 89-94 cannot be sustained for at least this reason.

The rationale provided in the Action in support of rejections of claims 40-53 and 60 over combinations of the Heilig patent with the Paul patent, the Clark patent and the Steuart patent is based upon a theory that persons skilled in the art would pluck ingredients out of the compositions described in the Paul patent, the Clark patent and the Steuart patent, place them in the composition described in the Heilig patent and deliver them to a treatment area using the aerosol delivery mechanism describe in the Heilig patent. Applicant submits that this

rationale fails to establish a *prima facie* case of obviousness under Section 103(a) for several reasons, the most predominant of which is that the combinations, even if made, fail to produce the subject matter recited in the pending claims. The primary reference cited in each combination, the Heilig patent, describes an aerosol composition and an aerosol delivery mechanism, while each of the pending claims in the present application recites an atomizing spray dispenser that is "not an aerosol device." As such, combinations of these secondary references with the Heilig patent for the purpose of modifying the disclosure of the Heilig patent to include additional ingredients described in the cited secondary references, does not overcome the insufficiencies in the Heilig patent to teach or suggest the subject matter of the present claims. The incorporation of ingredients from other references into the composition described in the Heilig patent would not alter that the Heilig delivery system is an aerosol delivery system. In view of the above, Applicant submits that the Action fails to make a *prima facie* case that the claimed subject matter is obvious over the combination of the Heilig patent with the Paul patent, the Clark patent or the Steauart patent, because each of these combinations would result in an aerosol-type delivery system, and the claims pending in the present application recite an atomizing spray dispenser that is "not an aerosol device."

With regard to the rejections of claims 74, 75, 87, 89 and 90-94 in the Action over combinations of the Heilig patent with the Ando patent, the Davies patent and the Hanson patent, the Examiner stipulates in the Action that, (1) "Heilig does not teach a pump spray dispenser... a pressure release device...[a] piston-style dispenser...[or] a manually actuated or reciprocating actuator spray delivery mechanism," (Office Action Page 12), (2) "Heilig does not teach a bag-in-can-style dispenser, wherein the pressurized compartment is a polymeric bag received inside a rigid can or wherein the pressure is maintained upon the composition by a pressurizing gas received in the can and externally to the bag." (Office Action Page 14), and (3) "Heilig does not teach a bag-in-can-style dispenser, wherein the pressurized compartment is a polymeric bag received inside a rigid can. Also, an elastic shape-memory bag wherein the pressure is maintained upon the composition by maintaining the bag in an expanded state is not taught."

The rationale provided in the Action in support of rejections of claims 74, 75, 87, 89 and 90-94 over combinations of the Heilig patent with the Ando patent, the Davies patent and

the Hanson patent is based upon assertions that a person skilled in the art would select one of the non-aerosol delivery mechanisms described in the secondary references to deliver the composition described in the Heilig patent, i.e., would substitute a non-aerosol delivery mechanism for the aerosol delivery mechanism described in the Heilig patent. Applicant submits that this rationale also fails to establish a prima facie case of obviousness under Section 103(a) for several reasons, the most predominant of which is that these combinations would render the subject matter described in the Heilig patent unsuitable for its intended purpose. The delivery system described in the Heilig patent involves a highly viscous ointment that can only be delivered as described therein if it is first dispersed in a very large amount of "inert volatile propellant" under high pressures to enable it to be delivered via an aerosol mechanism. Considering Examples 1 through 8 set forth in the Heilig patent at Columns 3-5, it is seen that each formulation includes at least 70% inert volatile propellant by weight, and some of the formulations include much higher proportions of inert volatile propellant, up to more than 95% by weight. Absent this aerosol mechanism, which relies on very high proportions of volatile propellants, the "ointment base" described in the Heilig patent could not be sprayed, and would therefore be unsatisfactory for its intended use. Therefore, Applicant traverses these rejections on the grounds that a person of ordinary skill in the art would not modify the references as asserted in the Action and because the combinations asserted in the Action would render the Heilig patent unsuitable for its intended purpose.

The Action cursorily states that one or more of the mechanisms described in the secondary references can be used to "spray a mixture of liquid and powder," (*See* Office Action, Page 12, line 17). The Examiner appears to be suggesting that an aerosol dispenser and a non-aerosol dispenser would have been expected by a person skilled in the art to be interchangeable for delivering any composition having liquid and solid components; however, Applicant traverses this implication. While aerosol delivery and non-aerosol delivery might be interchangeable mechanisms for delivery of compositions that are highly thinned (i.e., very low viscosity), such a composition would run off of a surface on which it is sprayed, and therefore would not conflict with the subject matter recited in the pending claims. It is important to note that the subject matter of the pending claims of the present

application, as amended, is directed to unique compositions that include a solid particulate material, and that have a specified combination of physical properties whereby, upon application of a coating of the composition to a skin treatment area, the coating "does not run off the skin treatment area." The cited references do not describe any compositions that meet the recited properties of sprayability and run-off resistance, that include solid particulate material and that are delivered using a non-aerosol spray delivery mechanism, as recited in the pending claims. Applicant submits that neither the Heilig reference, nor any other reference of record, teaches or suggests this unique combination of features.

Moreover, Applicant submits that a person of ordinary skill in the art at the time the present application was filed would not have had an expectation that he or she could successfully provide a composition as recited in the pending claims that would be sprayable using a non-aerosol spray delivery mechanism. In particular, no expectation of success can be derived from mere identification in the prior art of ingredients in a diaper rash treatment composition having significantly different physical properties and delivered using significantly different delivery mechanisms. Rather, there would be no expectation upon consideration of the prior art that any combination of ingredients described therein would have the properties of sprayability and run-off resistance recited in the pending claims. The rheological properties necessary to provide a non-aerosol spray dispensation system capable of atomizing a diaper rash treatment composition including a particulate solid material, while also providing for retention of the composition on the skin treatment area after delivery, are not taught, described or suggested in the cited references, nor are these features exhibited by the compositions described therein. This is clearly supported in the declarations submitted with Applicant's prior response, which are of record in the present case.

In addition to the above, the nonobviousness of the claimed subject matter is supported by the fact that multiple embodiments claimed in the present application have been recognized by experts in the relevant field as being breakthrough technology and a significant advance in the field. Indeed, as set forth in the Cawthon declaration of record in this case, products encompassed by the pending claims won the top vote award at the MedAssets' New Technology Fair in October 2005, at which 47 preselected high-tech healthcare companies presented their new products. The panel of judges of the competition

was composed of independent, neutral, technical specialists in various disciplines, including skin and wound care specialists. The grading criteria (based on a 4.00 scale) used by the judges were as follows, and the scores of the Applicant's sample compositions that are within the scope of the pending claims are set forth in parentheses:

Vendor's technology...	*Applicant's score*
- is new and can be considered "breakthrough" technology	***4.00***
- will have a significant impact on improving patient care	***3.93***
- will have a significant impact on improving labor efficiency	***3.91***
- will have a significant impact on improving cost efficiency	***3.84***
- will benefit the MedAssets' contract portfolio	***3.81***
-	

Applicant's Overall Score: 3.90 (#1 out of 47 companies)

Attached to the Cawthon declaration is a copy of the letter reporting the above-described result and detailing this information. Since that time, Applicant has also been awarded a $50,000 grant as a winner of the 2006 Vogt Awards, recognizing the technical innovation of multiple embodiments of the pending claims. Applicant submits that this evidence also strongly supports the non-obviousness of the claimed subject matter.

Applicant would also note that the present application claims priority to prior U.S. Patent Application No. 09/364,133 filed July 30, 1999, now U.S. Patent No. 6,627,178. Because the Paul patent is based on an application filed August 23, 1999, which is after the effective filing date of the present application, the Paul patent does not qualify as prior art to the claims of the present application.

In view of the above, Applicant submits that none of the combinations asserted in the outstanding Action supports a rejection of the claims of the present application under 35 U.S.C. §103. Withdrawal of these rejections is therefore respectfully requested.

Closing

In view of the above, Applicant respectfully submits that the rejections stated in the outstanding Action are overcome and that the present application, including claims 39-53, 57, 60, 74-76 and 87-94, is in condition for allowance. Action to that end is respectfully requested. If there are any remaining issues that can be addressed telephonically, the Examiner is invited to contact the undersigned to discuss the same.

Respectfully submitted,

By: _____

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